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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,900	04/12/2006	Palaniswamy Sunderraj	687-139	1726

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EXAMINER	
FINN, MEGHAN R	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
07/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/556,900	SUNDERRAJ ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *2-4,6-8,14-16 and 21-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,9-13,17-20 and 25-32* is/are rejected.

7)☒ Claim(s) *13 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/15/05; 1/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of group I (claims 1, 5, 9-13, 17-20, and 25-32) in the reply filed on March 18, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The previous action, dated October 18, 2007, did not address the multiple interpretations of "use" claims. However, since applicant elected group I, which was drawn to a method of treating, that will be taken as an indication that applicant intends the "use of triprolidine" to be a method of treating with triprolidine.

Claim Objections

Claim 13 is objected to because of the following informalities: The word sleep in the first line of claim 13 appears to be misspelled. Claim 13 currents reads "enhancing steep". Appropriate correction is required.

Claim 17 is objected to because of the following informalities: Claim 17 depends on any of claims 1-8, however claims 2-4, and 6-8 are withdrawn, and the claim cannot properly depend from a withdrawn claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 19-20, and 25-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of grogginess, drowsiness, and lethargy, does not reasonably provide enablement for prevention of such symptoms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The amount of experimentation necessary would be large (1) due to the lack of direction or examples towards prevention (2,3) The nature of the invention involves prevention of lethargy, which encompasses more than just sleepiness (4) and the state of the prior art is such that no known prevention of lethargy exists (5) and while the

relative skill of those in the art is high (6) the unpredictability of preventing a symptom such as lethargy is also high (7), due to the fact that lethargy can be caused by much more than lack of or bad quality sleep. Diet, stress, and conditions such as hypothyroidism result in lethargy, and a method of treatment which enhances sleep would not prevent lethargy from those sources. The breadth of the claims is large due to the fact that lethargy reads on more than just sleepiness (8).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 17-18, and 29-32 provide for the use of a consumable film comprising triprolidine, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 5, 17-18, and 29-32 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 9-13, 17-20, 26-28, and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monti et al (Histamine H1 Receptor Antagonists in the Treatment of Insomnia, cited on applicant's IDS) in view of Leung et al. (WO 00/18365, cited on applicant's IDS).

In claims 1 and 5, applicant claims the use of a consumable film comprising triprolidine as an active agent. For purposes of this examination this is being treated a method of treatment claim, as that was the group elected. Monti et al. teaches using triprolidine as a sleep aid (page 89, section 2 and table 1), and indicates that triprolidine produced sleepiness and decreased latency to stage 1 sleep (page 93, section 2.3). Monti et al. does not teach the formulation that triprolidine was administered by. However, Leung et al. teaches edible films, to be orally administered which can contain pharmaceutical agents (abstract), and teaches that they are fast dissolving (page 1, lines 5-10). It would be obvious to one of ordinary skill in the art at the time of the invention that to administer a sleep aid, a fast acting one would be preferable, and one that didn't require water to administer would also be preferable, for instance for use on air planes. Both of these two goals would be achievable with an orally consumable film such as taught by Leung et al. and thus it would be obvious to formulate the triprolidine as a consumable film for ease of administration and faster onset. Thus claims 1 and 5 are unpatentable over Monti et al. in view of Leung et al.

In claims 9-13, and 27 applicant claims a method of treating various sleep related problems by administering a consumable film comprising triprolidine prior to sleeping time. As discussed above Monti et al. teaches the use of triprolidine to treat insomnia, and it would be obvious to use the consumable film of Leung et al. for better administration. Thus claims 9-13, and 27 are also unpatentable over Monti et al. in view of Leung et al.

In claims 17-20, applicant claims the methods of claims 1, wherein the dosage of triprolidine is between 0.01mg-20mg or up to 20mg. Monti et al. teaches 5mg of triprolidine (page 93, section 2.3) and thus claims 17-20 are unpatentable over Monti et al. in view of Leung et al.

In claim 26 applicant claims the person is suffering from a sleep disorder. Monti et al. teaches usefulness of triprolidine for treatment of insomnia, which is a sleep disorder and thus claims 26 is also unpatentable over Monti et al. in view of Leung et al.

In claims 28 applicant claims the active ingredient is administered between 1 minute and 2 hours of sleeptime. Monti does not teach a time frame, however it would have been obvious to one of ordinary skill in the art at the time of the invention that a sleep aid should be administered shortly before bed, which would be well within the 2 hours claimed. Thus claim 28 is also unpatentable over Monti et al. in view of Leung et al.

In claim 30, applicant claims that the composition is an edible film, as discussed above, the film of Leung et al. is an edible film, meant to be orally consumed, and thus claim 30 is also unpatentable over Monti et al. in view of Leung et al. for the reasons discussed above.

In claim 31, applicant claims the drug is absorbable via the digestive tract. Monti et al. does not teach how the drug is absorbed, however the same composition would have the same effects and be absorbed the same way, and the absorption is a characteristic of the consumable film containing triprolidine which is obvious as discussed above, and thus claim 31 is also unpatentable over Monti et al. in view of Leung et al.

Claims 25, 29, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monti et al (Histamine H1 Receptor Antagonists in the Treatment of Insomnia, cited on applicant's IDS) in view of Leung et al. (WO 00/18365, cited on

applicant's IDS) in further view of Hamilton et al. (A comparison of Triprolidine and cyclizine on histamine (H1) antagonism, subjective effects and performance tests in man, cited on applicant's IDS) .

In claims 25 and 29, applicant claims the method of claim 1, wherein the triprolidine is in the form of triprolidine hydrochloride. Monti et al. does not specifically teach the hydrochloride salt form, although hydrochloride salt forms of active ingredients are very common, Hamilton et al. also discloses use of Triprolidine hydrochloride as a preferable formulation of triprolidine (page 441, column 2) and thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use the hydrochloride salt formulation of triprolidine. Thus claims 25 and 29 are unpatentable over Monti et al. in view of Leung et al. in further view of Hamilton et al.

In claim 32, applicant claims the method of claim 29, which is free of ingredients intended to sustain or prolong the release of the active agent. None of Leung et al., Monti et al., or Hamilton et al. teach agents which sustain or prolong release, and Leung et al. teaches a fast acting formulation which would be desirable in a sleep aid, and thus it would be obvious to avoid any sustaining or prolonging agents in such a formulation. Thus claim 32 is also unpatentable over Monti et al. in view of Leung et al. in further view of Hamilton et al.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614